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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,207	12/23/2005	Alan M. Fogelman	407T-301110US	9839

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	PAPER NUMBER
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,207	FOGELMAN ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-115* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-115* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election with traverse of SEQ ID NO:18 in the paper filed February 12, 2007 is acknowledged. The traversal is on the ground(s) that it is not proper to reject claims under 35 U.S.C. 121 on the basis of misjoinder of inventions. This is not found persuasive because there has been no rejection of the claims under 35 U.S.C. 121. Note that the court in Weber upholds the practice of withdrawing claims from consideration as drawn to nonelected inventions. See Weber at page 332. It is not seen how the restriction requirement in this application forces Applicants to file multiple divisional applications that are incapable of capturing the intended scope of the application. For example, 29 divisional applications each directed to one of the sequences recited in instant claim 7 are exactly equal in scope to claim 7 as originally filed. Finally, Applicants seem to be arguing that any number and types of inventions, e.g., mechanical, electrical, and chemical ad infinitum, could be filed as a single application and as a single claim (e.g., using "or" language or Markush-type language to join the inventions), and that the Office would be required to examine the application without restriction. Such a result is not contemplated by 35 U.S.C. 121, and is not supported by current or historical restriction practice. Applicants do not have a right to have examined in a single application multiple patentably distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. The Sequence Listing filed December 23, 2005 is approved.

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it claims priority under 35 U.S.C. 119 based upon PCT/US03/08899. However, this application was filed under 35 U.S.C. 371 based upon PCT/US03/08899 (see the Transmittal Letter filed December 27, 2004), which claim for priority is mutually exclusive to a claim for priority under 35 U.S.C. 119 based upon the same application.

4. The Application Data Sheet filed December 27, 2004 is objected to because it recites that this application is a national stage application of parent application 10/120,508. This claim for priority is improper, because only a PCT application can form the basis for a national stage application. The Application Data Sheet also indicates that foreign priority is being claimed based upon PCT/US03/08899, which, as noted in section 3 above, is not permitted.

5. The disclosure is objected to because of the following informalities: The claim for priority at paragraph [0001] is improper because the language "claims benefit" is language traditionally used for a claim for priority under 35 U.S.C. 119(e). However, claims for priority under 35 U.S.C. 119(e) must be based upon a provisional application. The language "claims... priority to" is not sufficient for a claim for priority under 35 U.S.C. 120, because the language does not specify the relationship, i.e. continuation, division, or continuation-in-part, between the instant application and parent application 10/120,508. See MPEP 201.11(III)(A) and (B). Appropriate correction is required.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 13, line 23. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

6. Claims 28, 32, 41-43, 50-54, 56-85, 87, and 90-115 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The word "and" should be inserted before the last member of the Markush group in claims 28, 32, 54, 82, and 115. Claims 32, 54, and 82 are indefinite because the recited groups are not phospholipids; rather, they are fatty acid groups. There is no antecedent basis in the claims for the phrases "said first protecting group" and "said second protecting group" in claims 41-43. Note that the independent claim uses the terminology "blocked" rather than "protecting group", and does not designate any blocking or protecting group as a "first" or "second" blocking or protecting group. The use of the term "comprises" in claim 50 is confusing. It is possible that the term should be replaced with "is in the form of". There is no antecedent basis in the claims for the phrase "said polypeptide" in claims 51-54. Note that the claims upon which claims 51-54 depend use the term "peptide", not "polypeptide". The phrase "said peptide" in claims 56-64, 66-78, and 83-85 is unclear because it is not clear to which of the two occurrences of "peptide" in the independent claim these claims are referring. Note that claim 55 uses "peptide" to refer to the entire active agent being administered to the mammal (see line 2) and to the amphipathic helical portion of that peptide (see line 3). Claim terminology needs to be clarified so that these two different uses of "peptide" can be distinguished from one another. For analogous reasons, the phrase "said peptide" in claims 91-96 is indefinite. There is no antecedent basis in the claims for the phrase "said polypeptide" in claims 79-82. Note that the claims upon which claims 79-82 depend use the term "peptide", not "polypeptide". There is no antecedent basis in the claims for the phrase "said organism" in claim 87. Note that claim 55, upon which claim 87 depends, uses the terminology

"mammal" rather than "organism". There is no antecedent basis in the claim for the phrase "said mammal" at claim 90, line 2. There is no antecedent basis in the claims for the phrase "said organism" in claims 97-100. Note that claim 90, upon which claims 97-100 ultimately depend, uses the terminology "mammal" rather than "organism". In claims 102, 103, and 105, it is believed that "said peptide" should be changed to "said polypeptide", consistent with the terminology in claims 1-28 in which "polypeptide" is used to refer to the entire active agent and "peptide" is used to refer to the amphipathic helical portion of the entire active agent. Claim 106 is indefinite because it requires mitigating or preventing a coronary complication associated with an acute phase response to an inflammation, and because it also requires the coronary complication to be a symptom of atherosclerosis. It is not clear, e.g., if the claim is requiring the mammal to have both inflammation and atherosclerosis, or if these two conditions are in the alternative to one another. Dependent claims 111 and 112, which specify numerous diseases which are not caused by or associated with atherosclerosis, imply that the mammal to be treated in claim 106 need not actually be afflicted with atherosclerosis. For analogous reasons, claim 113 is also indefinite.

7. Claims 11-14, 32, 33, 41, 54, 65-68, 82, and 100-115 are objected to because of the following informalities: At claim 11, lines 2 and 13, acetyl/Acetyl (Ac) is repeated. At claim 11, line 4, "fluorenecarboxylic" is misspelled. At claim 11, line 6, the "=" sign after "4,4" should be deleted. At claim 11, line 9, "dimethyl" is misspelled. At claim 11, line 10, "dioxocyclohexylidene" is misspelled. At claim 11, lines 3 and 12, t-boc/t-butoxycarbonyl(Boc) is repeated. At claim 11, lines 4 and 13, benzyloxycarbonyl/carbobenzoxy is repeated. At claim 11, lines 9 and 13, benzoyl is repeated. At claim 11, line 14, the second occurrence of "group"

after "hexyl" should be deleted. Similar errors occur in claim 41 and 65. At claim 12, line 2; claim 13, line 2; claim 14, line 6; claim 66, line 2; claim 67, line 2; and claim 68, line 6; "terminal" (first occurrence) should be changed to "terminus". At claim 12, line 4; claim 14, line 4; claim 66, line 4; and claim 68, line 4; "propionyl" is misspelled. At claim 32, line 3; claim 54, line 3; and claim 82, line 3; "undecanoyl" is misspelled. At claim 107, line 3, "and" (first occurrence) should be deleted. At claim 111, lines 5-6, the Markush members from "polymyalgia rheumatica" through "AIDS" are duplicates of Markush members found at lines 3-5 of the claim. At claim 115, line 3, a hyphen should be inserted between "histidine" and "rich". Appropriate correction is required.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 111 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the mitigation or prevention of coronary complications associated with the specified diseases other than Alzheimer's disease and AIDS, does not reasonably provide enablement for the mitigation or prevention of a coronary complication associated with Alzheimer's Disease or AIDS. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150 (CCPA 1977) and have been adopted by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among

these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. With respect to (1), the nature of the invention is the mitigation or prevention of a coronary complication associated with Alzheimer's Disease or AIDS. With respect to (2), the prior art does not disclose a connection between coronary complications and Alzheimer's Disease or AIDS. Alzheimer's disease lacks effective treatments, whereas treatments of AIDS are limited to inhibition of viral enzymes or receptors, or to vaccination. With respect to (3), the relative skill in the art is high. With respect to (4), the art is relatively unpredictable. There is no ability to predict effective treatments of Alzheimer's Disease or AIDS, or symptoms of these diseases, in the absence of at least some type of in vitro or in vivo experimentation. With respect to (5), the claims embrace the use of peptides, defined partially by structure and partially by function, to mitigate or prevent a coronary complication associated with Alzheimer's Disease or AIDS. With respect to (6) and (7), the specification provides no direction or guidance as to the mitigation or prevention of a coronary complication associated with Alzheimer's Disease or AIDS. The specification does not provide any theoretical model or proposed mechanism by which Alzheimer's Disease or AIDS can cause coronary complications, or by which Alzheimer's Disease or AIDS can be treated with peptides which comprise class A amphipathic helices. There are no working examples, in vivo or in vitro or otherwise, which model coronary complications caused by Alzheimer's Disease or AIDS. With respect to (8), the experimentation necessary to identify a relationship between coronary complications and Alzheimer's Disease or AIDS, and then to identify effective

treatments of such coronary complications, would be large. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-115 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-102 of U.S. Patent No. 6,930,085. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '085 patent clearly anticipate the instant claims.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

> patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

11. Claims 1-6, 25-28, 49, 50, 101, and 102 are rejected under 35 U.S.C. 102(b) as being anticipated by the Silkensen et al article (J. Pept. Res., Vol. 54, pages 449-457). The Silkensen et al article teaches the peptide Clu-29 (see Table 1), which corresponds to residues 2-17 of Applicants' SEQ ID NO:2, and Clu-30, which comprises residues 1-8 of Applicants' SEQ ID

NO:18. The peptides are in the form of an aqueous solution (see page 451, column 1, second full paragraph). Because the sequence of charged and nonpolar residues is the same in the Clu-29 peptide of the Silkensen et al article as in Applicants' peptide of SEQ ID NO:2, the peptide of the Silkensen et al article would have been expected inherently to form a G* amphipathic helix and to have sequence identity with apo J to the same extent claimed by Applicants. In view of the similarity in structure between the Clu-29 and Clu-30 peptides of the Silkensen et al article and Applicants' claimed peptides, the peptides of the Silkensen et al article are deemed inherently to protect the same phospholipids from oxidation by the same oxidizing agents to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the Clu-29 and Clu-30 peptides of the Silkensen et al article and Applicants' claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are novel and unobvious over those taught by the Silkensen et al article. An aqueous solution is a form suitable for oral administration to a mammal. Note that an intended use does not impart patentability to product claims where the product is otherwise anticipated by the prior art. With respect to instant claims 101 and 102, because the peptide is in the form of an aqueous solution, inherently it must be contained in a container at some point prior to or during its use in the assay.

12. Claims 1-7, 25-28, 49, 55-61, 83-99, 106, 107, and 109-115 are rejected under 35 U.S.C. 102(e) as being anticipated by the WO Patent Application 2002/22161. The WO Patent Application '161 teaches administering clusterin, i.e. Apo J, to in order to treat or prevent atherosclerosis and underlying and/or related diseases, i.e. those diseases which result from disturbed complement function. Causes of disturbed complement function include, e.g., auto-immune diseases, infectious diseases, neoplastic diseases, and inflammatory diseases. The

clusterin can be administered orally, and can be administered in combination with a pharmacologically acceptable excipient. One or more complement components are estimated in the blood of patients to be treated in order to establish the underlying or related defect of the patient's atherosclerosis. See, e.g., page 20, lines 17-21; page 24, lines 2-18; page 29, lines 3-20; page 31, lines 17-26; claims 1, 4, 6, 8, 14-19, 25. Clusterin/apo J inherently comprises an amphipathic helical peptide as defined in Applicants' claims. In view of the similarity in structure and function between the clusterin/Apo J of the WO Patent Application '161 and Applicants' claimed peptides, the clusterin of the WO Patent Application '161 is deemed inherently to protect the same phospholipids from oxidation by the same oxidizing agents to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the clusterin of the WO Patent Application '161 and Applicants' claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are novel and unobvious over that taught by the WO Patent Application '161.

13. Claims 50 and 101-105 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 2002/22161. Application of the WO Patent Application '161 is the same as in the above rejection of claims 1-7, 25-28, 49, 55-61, 83-99, 106, 107, and 109-115. The WO Patent Application '161 does not teach its modulators in kit form, optionally in unit dosage form and with instructions for use. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to provide the modulators of the WO Patent Application '161 in kit form, optionally in unit dosage form and with instructions for use, because it is routine in the pharmaceutical arts to provide therapeutic agents in kit form in unit dosage form

and with instructions for use for ease of storage, transport, measurement, and administration of the therapeutic agents.

14. Claims 1-8, 25, 27, 28, 49, 55-62, 83, 86-100, 106, 107, 109, and 112-115 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 91/05043. The WO Patent Application '043 teaches an isolated protein having the amino acid sequence recited in claim 17. Residues 113-122 correspond to Applicants' SEQ ID NO:9; residues 336-353 correspond to Applicants' SEQ ID NO:2; and residues 358-368 correspond to Applicants' SEQ ID NO:9. The isolated protein can be combined with a pharmaceutically acceptable excipient (see claim 22) and can be administered to treat conditions such as inflammation or immunological disorders (see claim 32). In view of the similarity in structure and function between the cytolysis inhibitor of the WO Patent Application '043 and Applicants' claimed polypeptides, the cytolysis inhibitor of the WO Patent Application '043 is deemed inherently to protect the same phospholipids from oxidation by the same oxidizing agents to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the cytolysis inhibitor of the WO Patent Application '043 and Applicants' claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are novel and unobvious over that taught by the WO Patent Application '043. With respect to instant claim 3, note that this claim limits the size of the amphipathic helical peptide which forms part of Applicants' claimed polypeptide, but does not limit the size of the claimed polypeptide. With respect to instant claims 106, 107, 109, and 112-115, because the same active agent is administered to the same patient by the same method steps, inherently a coronary complication associated with an

acute phase response to inflammation will be prevented in the method of the WO Patent Application '043 to the same extent claimed by Applicants.

15. Claims 50, 101-103, and 105 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 91/05043. Application of the WO Patent Application '043 is the same as in the above rejection of claims 1-8, 25, 27, 28, 49, 55-62, 83, 86-100, 106, 107, 109, and 112-115. The WO Patent Application '043 does not teach its cytolysis inhibitor in kit form, optionally in unit dosage form and with instructions for use. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to provide the cytolysis inhibitor of the WO Patent Application '043 in kit form, optionally in unit dosage form and with instructions for use, because it is routine in the pharmaceutical arts to provide therapeutic agents in kit form in unit dosage form and with instructions for use for ease of storage, transport, measurement, and administration of the therapeutic agents.

16. Claims 1-6, 25, 27, 28, 55-60, 86-95, 97-100, 106, 107, and 112-115 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 00/34469. The WO Patent Application '469 teaches a clusterin-related peptide having the sequence recited in claims 10 and 16. The peptide is used to treat diseases or conditions such as restenosis or atherosclerosis (see claim 24). Residues 2-14 of the WO Patent Application '469's peptide of claim 16 correspond to residues 4-16 of Applicants' SEQ ID NO:2, with the exception of the S/N at position 8 of the WO Patent Application '469/position 10 of Applicants' SEQ ID NO:2. Because the sequence of charged and nonpolar residues is the same in the corresponding sections of the peptide of the WO Patent Application '469 and in Applicants' peptide of SEQ ID NO:2, the peptide of the WO Patent Application '469 would have been expected inherently to form a G* amphipathic helix

and to have sequence identity with apo J to the same extent claimed by Applicants. In view of the similarity in structure and function between the peptide of the WO Patent Application '469 and Applicants' claimed polypeptides, the peptide of the WO Patent Application '469 is deemed inherently to protect the same phospholipids from oxidation by the same oxidizing agents to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptide of the WO Patent Application '469 and Applicants' claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are novel and unobvious over that taught by the WO Patent Application '469.

17. Claims 25, 49, 50, 83, 101-103, 105, and 109 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 00/34469. Application of the WO Patent Application '469 is the same as in the above rejection of claims 1-6, 25, 27, 28, 55-60, 86-95, 97-100, 106, 107, and 112-115. The WO Patent Application '469 does not teach its clusterin-related peptide in combination with a pharmaceutically acceptable excipient or in kit form, optionally in unit dosage form and with instructions for use. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to combine the clusterin-related peptide of the WO Patent Application '469 with a pharmaceutically acceptable excipient or to provide the clusterin-related peptide of the WO Patent Application '469 in kit form, optionally in unit dosage form and with instructions for use, because it is routine in the pharmaceutical arts to combine therapeutic agents with pharmaceutically acceptable excipients or to provide therapeutic agents in kit form in unit dosage form and with instructions for use for ease of storage, transport, measurement, and administration of the therapeutic agents.

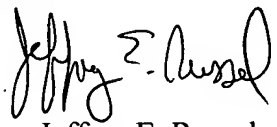
18. Claims 9-18 and 63-75 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 00/34469 as applied against claims 1-6, 25, 27, 28, 55-60, 86-95, 97-100, 106, 107, and 112-115 above, and further in view of Borovsky et al (U.S. Patent No. 5,358,934). The WO Patent Application '469 does not teach modifying the N-terminus of its clusterin-related peptide with acetyl and/or modifying the C-terminus of its clusterin-related peptide with amide. Borovsky et al teach acetylating the N-terminus and amidating the C-terminus of peptides in order to inhibit proteolysis by metabolic enzymes (see column 2, line 64 - column 3, line 2). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to modify the clusterin-related peptide of the WO Patent Application '469 by acetylation and amidation as taught by Borovsky et al because such modification would have the benefit of preventing proteolysis by metabolic enzymes and would thereby lengthen the activity of the peptide.

19. Claims 26, 84, 85, and 104 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 00/34469 as applied against claims 25, 49, 50, 83, 101-103, 105, and 109 above, and further in view of Stern et al (U.S. Patent No. 6,086,918). The WO Patent Application '469 does not teach oral administration of its clusterin-related peptide. Stern et al teach carrier compositions whereby peptides can reliably be administered orally, thereby avoiding the inconvenience and discomfort of other modes of administration, e.g., by injection or nasally. See, e.g., the Abstract; column 1, lines 46-65, and column 2, lines 16-22. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to administer the clusterin-related peptide of the WO Patent Application '469 using the carrier

compositions of Borovsky et al because such carrier compositions would provide the benefit of being able to administer the peptides orally rather than nasally or by injection.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

March 14, 2007